

IN THE UNITED STATES COURT DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

UNITED STATES OF AMERICA,)	
)	Criminal No. 1:14CR397
v.)	
)	Judge Anthony J. Trenga
HANOCH DAVID STEIN,)	
)	Sentencing: August 14, 2015
Defendant.)	

HANOCH DAVID STEIN'S SENTENCING MEMORANDUM

Defendant, Hanoch David Stein, by and through his counsel, respectfully submits this sentencing memorandum to assist the court in determining the appropriate sentence. Pursuant to a plea agreement, Mr. Stein has pled guilty to conspiracy, in violation of Title 18, United States Code, Section 371, and the unlicensed wholesale distribution of prescription drugs, in violation of Title 21, United States Code Sections 331(t), 333(b)(1)(D), and 353(e)(3)(B). We respectfully submit that this Court sentence Mr. Stein to probation.

Consideration of the factors of 18 U.S.C. § 3553(a) leads to the conclusion that probation is an appropriate sentence for several reasons. First, Mr. Stein did not join TC Medical Group's enterprise knowing that its activity was illegal, and he did not understand the full extent of the company's illegal conduct until reading the indictment. Second, Mr. Stein occupied the lowest position in the company. Mr. Stein acted as no more than a packaging agent, and in this capacity, had no strategic involvement in the business. Third, Mr. Stein is a productive member of society. He has no criminal history and has maintained steady employment for nine years as a warehouse manager for a dental wholesale supplier. Fourth, Mr. Stein is a loving and caring father of his eleven-year-old daughter and the sole financial support to both his daughter and his ex-wife. As the attached letters provide, Mr. Stein is a good son, brother, and friend. He

consistently involves himself in charity and in his community. Finally, Mr. Stein is deeply remorseful for his entanglement in this criminal activity, and his arrest and convictions have both humiliated and devastated him. Going forward, he fully intends to follow the law and to continue being a productive member of society.

The Guideline range suggested by the PSR should not be used to determine Mr. Stein's sentence. The Guideline range grossly overstates the loss amount foreseeable to Mr. Stein. Thus, it is not indicative of an appropriate sentence. For the reasons stated herein, probation is a fair and just sentence.

I. FACTUAL BACKGROUND

A. Mr. Stein

Mr. Stein was born in Toronto, Canada to Arthur and Leslie Stein. Mr. Stein's family moved to Israel when he was just five years old. Mr. Stein moved back to Canada when he was nineteen years old but maintains a firm and close connection to his parents and five siblings. (Ex. 1, Letters from Esther, Moshe, and Leslie.) He was married at the age of twenty-two and had a daughter, Oriyah, in 2004. He divorced at the age of twenty-eight but remained steadfast in his commitment to support his ex-wife and daughter, determined to ensure not only their survival, but to provide his daughter with a religious education and allow his ex-wife the freedom to be an active mother to her. Although not required to by law or any agreement, Mr. Stein provides total economic support to his ex-wife and daughter. (Ex. 2, Letter from Merav.) He pays for his ex-wife's and daughter's rent, car lease, clothing and food, tuitions, babysitting, and every other necessity. (Ex. 2, Letter from Merav.) Indeed, a significant portion of his earnings goes directly to support his ex-wife and daughter.

Mr. Stein joined North American Dental, a wholesale dental supply company, in 2006 to help set up the Baltimore, Maryland warehouse. This short term move turned into close to a decade, as Mr. Stein set up the warehouse and became the manager. Despite his move and busy work schedule, Mr. Stein has continued to maintain close contact with his daughter and ex-wife, and to support them financially.

As a warehouse manager for North American Dental, Mr. Stein was, and continues to be, responsible for shipping and receiving substantial amounts of inventory each year. His employers characterize him as “loyal” and dedicated to his work. (Ex. 3, Letter from North American Dental, Zahava Kalfa.)

Despite living far from his eleven-year-old daughter, Mr. Stein makes constant efforts to be involved in her life and plays an essential role in her stability and upbringing. (Ex. 2, Letter from Merav.) He is in touch with her throughout the course of each day, providing her with “support, comfort, love and discipline,” and expends tremendous efforts to see her. (Ex. 2, Letter from Merav; Ex. 4, Letter from R. Lefkowitz.) As a devoted father, his daughter involves him “in every detail of [her] day” (Ex. 5, Letter from Oriyah.), “her social and emotional wellbeing, as well as her schoolwork.” (Ex. 4, Letter from R. Lefkowitz.) In Oriyah’s words, “I learned that my father would stop at nothing to make me happy.” (Ex. 5, Letter from Oriyah.) The months since Mr. Stein’s arrest have been particularly difficult for Oriyah, as Mr. Stein cannot travel to Canada to visit her. (Ex. 5, Letter from Oriyah; Ex. 2, Letter from Merav.)

Mr. Stein has no prior criminal history, and throughout his life, the one distinct quality used to describe him is his big heart. (Ex. 1, Letter from Tzivia.) He is a deeply caring, devoted, and charitable man, one whose generosity knows no bounds. (Ex. 1, Letters from Leslie and Moshe.) Despite not owning a car, home, and barely covering his own necessities, Mr. Stein

extends all that he has to those in need, and what he cannot offer in money, he offers in time and effort. (Ex. 1, Letters from Leslie, Rivka, Esther, and Tzivvia.) One example is his regular volunteering of his warehouse expertise to a charity that packages and delivers food and necessities to the poor. (Ex. 6, Letter from Ahavas Yisroel.)

Mr. Stein is a productive member of society.¹ He has maintained steady employment and has taken it upon himself to hire those in the community who others would not. (Ex. 7, Letter from Y. Kusher.) When not at work, Mr. Stein regularly attends classes with his Rabbi because God, morals and ethics, and their role in his life are of great importance to him. (Ex. 4, Letter from Rabbi Lefkowitz.)

B. Mr. Stein's Offense

Mr. Stein's offense must be viewed in context. Mr. Stein was recruited to help with shipping at TC Medical Group because of his experience successfully managing the warehouse of a growing gray market dental supply company, North American Dental, where he receives and breaks down large shipments of non-prescription dental supplies, repackages them, and ships them to dentists and retail stores. It is important to note that Mr. Stein deals with supplies, not drugs, and the supplies do not require cold storage. With the knowledge that Mr. Stein possessed this expertise, the CEO of TC Medical Group asked if Mr. Stein would help with packaging for its business. While Mr. Stein remained firmly committed to his day job, he agreed to take on this after-hours work with the hopes that this extra income, though a mere fifteen dollars per box shipped, would help support himself, his ex-wife, and his daughter.

¹ As further evidence of Mr. Stein's rehabilitation, after being indicted, he unilaterally decided to file his tax returns for prior years of unpaid taxes. While he does not have the money to make the full payment due at this time, he has retained tax counsel and expects to cooperate fully to work out an agreement with the IRS.

Mr. Stein worked for TC Medical Group out of his rented home. After work, Mr. Stein would pick up packages from a postal store, unpack the contents, take inventory of the products, and ship them per the instructions of superior TC Medical Group employees. (Ex. 8, Emails.)

Mr. Stein understood that the objective of TC Medical Group was primarily to receive pharmaceuticals manufactured for sale overseas and to sell them on the gray market to domestic physicians and clinics. Mr. Stein's role in this endeavor was similar to his role at North American Dental, though unlike the products sold by North American Dental, TC Medical Group's products involved prescription pharmaceuticals, the wholesaling of which requires FDA approval and licensing.

At first, Mr. Stein was unaware of the illegality of TC Medical Group's activity. He did not think much of the company's business because his work consisted of the very acts he carried out lawfully in his employment at North American Dental, namely, receiving, taking inventory, repackaging, and reshipping product. In considering his continued work for TC Medical Group, it is important to be mindful of the fact that as a shipper, both in his daytime employment as well as for TC Medical Group, Mr. Stein's job was limited to shipping the package irrespective of its contents, much like a postal carrier or a FedEx driver. The type and nature of product shipped carried no significance, which contributed to Mr. Stein's inattention to the legality of his conduct. Slowly, however, through the confluence of specific comments, Mr. Stein began to realize that TC Medical Group was operating illegally.

Mr. Stein's role at TC Medical Group was menial and inferior. He did not participate in any planning, coordinating, or establishing of this enterprise. (Ex. 8, Emails.) He played no part in acquiring the products sold, acquiring customers for the company, marketing any of its products, or in falsely advertising their FDA approval. He acted in no leadership or managerial

role whatsoever, save for a friend whom he paid to help with packaging when he was either out of town or unable to work because of the commitments of his day job. TC Medical Group sales personnel would email him with instructions as to when and where packages would arrive, and then direct Mr. Stein where to send them. (Ex. 9, Instant Messages.) On occasion, the parcels Mr. Stein received were checks from customers which he was likewise directed to send per TC Medical Group employees' instruction. (Ex. 9, Instant Messages.)

In this limited capacity, he was unaware of the breadth of this company, many of its employees, or of their activities. (Ex. 8, Emails.) He was similarly ignorant as to the value of the products he handled and of the profit that TC Medical Group earned from their sale. So inconsequential was he to this company that on more than one occasion, he was informed that the company was prepared to replace him. (Ex. 10, Instant Messages.) His minor and insignificant position is further evidenced by the constant verbal abuse he received from the more prominent employees of the company as well as by the meager amount he was paid compared to the overall financial success of TC Medical Group and the earnings of other TC Medical Group employees. (Ex. 10, Instant Messages.)

Mr. Stein does not deny that he shipped products intended for sale outside the United States. Nor does he deny that he had enough warning signs of the illegality of his efforts. He does, however, object to any contention that the products he shipped were unsafe. There is no credible evidence to the contrary.²

Mr. Stein also assumed that as he followed the direct instructions of his superiors, he was taking the necessary precautions to ensure the safety of the products. For example, he had been

² We object to paragraph 51 in the PSR, which suggests that Mr. Stein might have been aware that the drugs at issue were unsafe. But the PSR itself concedes "the Government does not have information on specific harms inflicted on these unsuspecting patients...."

advised that Botox and similar products could remain at room temperature for the duration of two to six weeks to remain safe and effective. Additionally, he was vigilant in his care of products which required refrigeration and perfected the shipping of these products so they would arrive at their destinations cold and dry. As the PSR recounts, he repeatedly contacted his superiors at TC Medical Group about receiving warm or wet products because he was concerned that the product would be either ineffective or harmful and did not want to ship it as such; he shipped product only if its shipment was approved by his superiors.

II. ARGUMENT

A. Mr. Stein should receive a downward variance based on the factors of 18 U.S.C. § 3553(a).

As delineated in *United States v. Gall*, 552 U.S. 38, 46 (2007), *United States v. Booker*, 543 U.S. 220 (2005) puts an end to the presumption that the Federal Sentencing Guidelines mandate each defendant's sentencing. *United States v. Hughes*, 401 F.3d 540 (4th Cir. 2005), outlines the process through which the Court determines a defendant's sentence. The Court "shall first calculate (after making the appropriate findings of fact) the range prescribed by the guidelines. Then the court shall consider that range as well as other relevant factors set forth in the guidelines and those factors set forth in § 3553(a) before imposing the sentence." *Id.* at 546. If the Guideline range does not serve those factors, as is the case here, the court may instead impose a non-Guideline sentence. The relevant factors set out in § 3553(a) are:

(1) the nature and circumstances of the offense and the history and characteristics of the defendant;

(2) the need for the sentence imposed—

(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;

- (B) to afford adequate deterrence to criminal conduct;
- (C) to protect the public from further crimes of the defendant; and
- (6) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct;

A non-Guideline sentence of probation pursuant to § 3553(a) is appropriate in this case.

1. The nature and circumstances of the offense and the history and characteristics of the defendant.

Mr. Stein occupied the lowest position in the conspiracy.³ He was unaware of the depth and breadth of TC Medical's fraud and of his participation in it; his position in TC Medical Group was narrow and subordinate; he was viewed and treated as an insignificant member in this enterprise; and he was compensated not based on profits of the company, but on each parcel shipped (much akin to FedEx). The government attributes a much more significant role to Mr. Stein than is warranted based on the facts that Mr. Stein was the original warehouse person for the company and that a large quantity of product went through his warehouse. But there were several others performing warehouse functions in different parts of the country doing exactly what Mr. Stein was doing, some of whom were not even charged in the conspiracy. There was nothing unique about Mr. Stein's role in Baltimore, Maryland.

The commentary to U.S.S.G. § 3B1.2 expressly defines a minor participant as one who is "less" culpable and includes an explicit characterization of a minimal role as one where a defendant has a "lack of knowledge or understanding of the scope and structure of the enterprise and of the activities of others." No authority supports a per se disqualification of a defendant from a minimal or minor role adjustment on the sole basis that the defendant's role, no matter

³ We object to paragraph 55 of the PSR, which characterized Mr. Stein as an "average" participant. He was a minor participant.

how small, was necessary for the enterprise to succeed. In fact, in the unpublished decision of *U.S. v. Brown*, 213 F.3d 643, 2000 WL 301045 at *1 (9th Cir. 2000) (unpublished table decision), the Ninth Circuit reversed the district court's denial of a §3B1.2 adjustment, holding it was error to deny the two level decrease on the basis that the defendant was an "essential participant." The correct focus is "[the defendant's] culpability relative to that of the co-participants in the bank fraud. . . . A person may be substantially less culpable even if he or she was an essential participant of the crime." *Id.* (citing *United States v. Hill*, 953 F.2d 452, 461 (9th Cir. 1991)); *see also United States v. Petti*, 973 F.2d 1441, 1447 (affirming the district court's conclusion that defendant's role was "minimal" under U.S.S.G. § 3B1.2 even though the defendant understood the full scope of the conspiracy and performed "critical functions" as a member of the conspiracy).

The Fourth Circuit affirms downward variances under § 3553(a) based on considerations of the defendant's personal characteristics, lack of criminal history, low risk of recidivism, employment, and positive role in his family and community. *United States v. Smith*, 275 Fed.Appx. 184, 187 (4th Cir. 2008), *United States v. Pauley*, 511 F.3d 468, 475 (4th Cir. 2007), *United States v. Habbal*, No. 01:05CR083 (JCC), 2005 WL 2674999, at *4 (E.D. Va. 2005). Mr. Stein's participation in this criminal activity is an anomaly. He has no criminal history and has otherwise led a productive life. He has maintained steady employment, close ties with his family, and is involved in his community.

A sentence of imprisonment will likely destroy Mr. Stein's ability to continue to be a productive member of society. Mr. Stein will lose a longstanding managerial position he has maintained for nine years and likely prohibit, or at least significantly diminish, his chances of meaningful employment upon release.

Mr. Stein's responsibility to his ex-wife and daughter provides another crucial reason for a variance and a non-Guidelines sentence of probation. As the sole provider for his ex-wife and daughter, the possibility of incarceration not only punishes Mr. Stein, but, as his ex-wife explains, "I need David to keep working for my daughter and me to survive, literally," to speak nothing of the great emotional toll that his absence would have on young Oriyah, her development, and her relationship with her father. (Ex. 2, Letter from Merav.)

2. The need for the sentenced imposed-
(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense.

While the PSR recommends a Guideline range of 26,⁴ "the Guidelines are only one of the factors to consider when imposing a sentence, and § 3553(a)(3) directs the judge to consider sentences other than imprisonment." *Gall*, 552 U.S. at 59. Given the totality of Mr. Stein's circumstances and his history, a sentence of probation addresses § 3553(a)'s requirement for a "sufficient but not more than necessary" sentence to reflect the seriousness of Mr. Stein's offense and to provide just punishment.

The FDA ensures the safety and efficacy of pharmaceuticals sold domestically and is crucial to the wellness of the American public, but to punish Mr. Stein with incarceration would be unfairly lending his involvement greater weight than his limited participation warrants. Further, the gravity of this offense lies in its potential harm to the consumer. In this instance, not only was Mr. Stein unaware of any harm that could result from his actions, but the evidence suggests he was helping to ensure the appropriate handling of the product. It is critical to note that Mr. Stein never intended to undermine the safety of the American public.

⁴ We object to paragraph 63 of the PSR, which adds a two level bump for a substantial part of the scheme being committed from outside the United States or involving sophisticated means. This was not contemplated by the government and, in any event, is encompassed by the underlying offense.

In this instance, probation is an appropriate sentence to punish Mr. Stein. In *Gall*, the court affirmed the district court's sentence of probation because, given the totality of the circumstances, the defendant's history, and his minor role in the enterprise, "a sentence of imprisonment may work to promote not respect, but derision, of the law if the law is viewed as merely a means to dispense harsh punishment without taking into account the real conduct and circumstances involved at sentencing." *Id.* at 54 (quoting the district court). Moreover, the sentence of probation imposes "several standard conditions that substantially restrict [one's] liberty," providing Mr. Stein with just punishment for his offense. *Id.* at 48.

(B) to afford adequate deterrence to criminal conduct.

Already serving as a punishment and deterrent, Mr. Stein's conviction has profoundly affected him, indelibly marked his memory and blemished his reputation. The embarrassment he has suffered as well as the looming fear that he may lose all that he has worked to accomplish makes it highly unlikely that he will ever allow himself to become entangled in criminal activity again.

As a sensitive family man, Mr. Stein has also witnessed the heart wrenching toll that his prosecution has had on his loved ones. His mother in Israel is ill, fighting for her life against breast cancer. Because of his current position, he is barred from leaving the country and unable to visit his mother. He is pained and remorseful for the added stress that his arrest and the looming threat of incarceration has caused his already weakened mother.

Mr. Stein's pride and joy, his daughter Oriyah, has expressed depression and tremendous sadness since Mr. Stein's arrest. His current position has upset the frequent visiting schedule that he has set so that he may play a vital and constant role in his daughter's life. Prior to his arrest, Mr. Stein vigilantly attended every major event in her life, including each birthday. Mr. Stein is

tormented by the fact that he may no longer be able to realize this tradition and self-imposed duty. The complete humiliation, pain, and disruption to Mr. Stein's life since his arrest has served to punish him and preclude any future criminal activity.

(C) to protect the public from further crimes of the defendant.

Mr. Stein does not pose a risk to the public. His involvement in the criminal activity of TC Medical Group is the exception to his otherwise law abiding life. He did not seek out this criminal activity; TC Medical recruited him. Nor was he aware of TC Medical's illegal conduct when he became involved in it. This ordeal has served as a well-learned lesson for Mr. Stein to thoroughly investigate future business opportunities to ensure their compliance with the law and to withdraw at the first sign of troubling conduct.⁵

3. The need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct.

Also listed among the factors of § 3553(a) is the need to avoid disparate sentences amongst similarly charged defendants. Although the facts of each case are different, defendants guilty of like offenses have received sentences of probation. In the recent case of *United States v. Gallant Pharma Int'l., Inc.*, No. 1:13CR00130-001, 2014 WL 2573067 (E.D. Va. 2014), the defendant was sentenced to probation for importation contrary to law, introducing misbranded drugs into interstate commerce and the unlicensed wholesale distribution of prescription drugs.

In *United States v. Harvey Whitehead*, Case No. 1:13-CR-130-7 (E.D. Va. 2014) the defendant was sentenced to two years of probation for each offense of unlicensed wholesale of pharmaceuticals and of introducing misbranded drugs into interstate commerce to run

⁵ Mr. Stein was willing to cooperate in the investigation, but the government insisted that he agree not to argue the draconian guideline sentence it sought. It was not until the week prior to trial that the government agreed to allow Mr. Stein to argue the loss amount. At that point, Mr. Stein pled guilty.

concurrently with each other.⁶ Whitehead was employed by Gallant Pharma International, Inc., which, like TC Medical, procured authentic pharmaceuticals intended for sales overseas and illegally sold them to physicians in the United States. The products were similarly misbranded, maintained, and stored. Like Mr. Stein, this defendant stored the cold chain drugs in a refrigerator at his residence, only unlike Mr. Stein, this defendant participated not only in storing and shipping these products, but in marketing and sales of the product as well.

- Michael Merriam sold products in this same scheme. He was sentenced to one year probation and a \$10,000 fine for introducing misbranded drugs into interstate commerce.⁷ *United States v. Merriam*, Case No. 1:13-CR-370-1 (E.D.Va. 2014).
- Lisa Coroniti (No. 1:13-CR-130-9): On November 6, 2013, Coroniti appeared before Judge Hilton and pleaded guilty to a Criminal Information charging Introduction of Misbranded Drugs. On April 4, 2014, Coroniti was sentenced to 2 years' probation.
- Patricia Durr (No. 1:13-CR-130-8): On November 6, 2013, Durr appeared before Judge Hilton and pleaded guilty to a Criminal Information charging Introduction of Misbranded [Drugs]. On March 28, 2014, Durr was sentenced to 2 years' probation, with the special condition she serve 6 months of home detention.

Defendants in other jurisdictions have similarly received sentences of probation for this type of activity:

⁶ The loss amount attributable to the defendant in this case was between \$1 million and \$2.5 million.

⁷ The loss amount attributable to the defendant in this case was between \$30,000 and \$70,000.

- *United States v. Vo*, Case No. 13-cr-0048 (W.D. Ky. 2013) (sentencing Kentucky physician to one year of probation and \$50,000 restitution for knowingly importing non-FDA approved Canadian birth control and prescribing to patients).
- *United States v. David J. Fishman*, Case No. 13-mj-8016 (N.D. Ohio 2013) (sentencing an Ohio physician to one year probation for knowingly importing lower-cost, but identical, oncology drugs from a Canadian distributor for use in his practice).
- *United States v. Behe*, Case No. 12-cr-00009 (E.D. Mo. 2012) (sentencing a vice-president of a drug company to five years probation for knowingly importing from a UK wholesaler cancer drugs, including cold-chain drugs).
- *United States v. Anthony Galea*, Case No. 10-cr-307 (W.D.N.Y. 2010) (sentencing a Canadian physician to one year probation for knowingly importing foreign human growth hormone and steroid, even though such treatments would be legal in Canada and the bottles retained the original foreign language labels).
- *United States v. Verhage, Orr and Biegert*, Case No. 13-cr-105 (W.D. Mich. 2013) (sentencing defendant pharmacists to no imprisonment and a \$30,000 fine for knowingly receiving returned drugs from nursing homes and restocking them into other bottles that did not contain accurate lot numbers or expiration dates).

B. The loss amount does not reflect Mr. Stein's conduct.⁸

The PSR advises that the loss amount attributable to Mr. Stein's conduct is between \$7 million and \$20 million based on the gross proceeds to TC Medical Group from the products that Mr. Stein shipped out. This leads to a range enhanced by twenty levels. However, this value

⁸ We object to paragraph 62 of the PSR on the grounds that the loss amount stated was not reasonably foreseeable to Mr. Stein.

inaccurately addresses Mr. Stein's place within the scope of the conspiracy, the reasonable foreseeability of the acts of his co-conspirators, as well as the reasonably foreseeable pecuniary harm of Mr. Stein's acts.

1. The loss amount does not reflect acts reasonably foreseeable to Mr. Stein.

"In order to attribute to a defendant for sentencing purposes the acts of others in jointly-undertaken criminal activity, those acts must have been within the scope of the defendant's agreement and must have been reasonably foreseeable to the defendant." *United States v. Gillam*, 987 F.2d 1009, 1012-13 (4th Cir. 1993) (in its discussion of § 1B1.3). The sentencing court is charged with making particularized finding as to both the scope of the activity that the defendant agreed to undertake, as well as the reasonable foreseeability of the illegal actions of co-conspirators. *United States v. Bolden*, 325 F.3d 471, 499 (4th Cir. 2003). The Commentary to U.S.S.G. § 1B1.3 directs that for conduct not within the scope of the defendant's agreement, "such conduct is not included in establishing the defendant's offense level." Application Note 1. Moreover, "the mere knowledge that criminal activity is taking place is not enough for sentence enhancement under § 1B1.3. The rule does not hold accountable any person who reasonably suspects that criminal activity is taking place, regardless of their involvement. To hold a defendant accountable for the crime of a third person, the government must establish that the defendant agreed to jointly undertake criminal activities with the third person, and that the particular crime was within the scope of that agreement." *United States v. Egbuomwan*, 992 F.2d 70, 74 (5th Cir. 1993). Similarly, as in *United States v. White*, 77 Fed.Appx. 678 (4th Cir. 2003), courts have vacated sentences where the lower court did not make a particular finding as to the specific loss attributable to the defendant within the conspiracy, noting that involvement in a

conspiracy does not automatically impute the loss of the entire conspiracy to the defendant. *Id.* at 681-82.

Presumably, the basis of the PSR's conclusion are loss findings from other fraud on the FDA cases like *United States v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996), and *United States v. Shulman*, 107 F.3d 868, 1997 WL 82620, at *6-*7 (4th Cir. 1997) (unpublished table decision), where the loss amount was measured by the gross proceeds to the company. However, as the *Shulman* court explains, the first step in calculating the loss is an inquiry into the defendant's "relevant conduct." *Id.* at *6. In stark contrast to those cases, where the defendants were the presidents or CEOs of their companies, Mr. Stein was the most inferior of this company's employees. Mr. Stein could not have known what his superior members of TC Medical Group knew. He did not know that there were any safety issues. He did not know the prices of the drugs or the profit obtained by TC Medical. He did not know the scope or the exact nature of the conspiracy. He did not play any role in establishing this scheme. While he eventually came to question the legitimacy of certain acts of the company, such as an awareness of the illegality of wholesaling pharmaceuticals without a license, he did not agree to participate in illegally purchasing products for wholesale, falsely advertising to obtain customers, choosing the means by which the product would enter the United States illegally, or illegally selling the product.⁹ These acts committed by his coconspirators were not reasonably foreseeable to him. Thus, the gross value to the company from the sale of the products he shipped cannot correctly be attributed to Mr. Stein's activity.

2. The loss amount does not reflect the reasonably foreseeable pecuniary harm of Mr. Stein's offense.

⁹ In fact, Mr. Stein arrived at his home when the search was underway. He pulled into the driveway, parked, and introduced himself to the agent.

The Application Notes 3(A)(i), (iii) and (iv) in the Commentary to U.S.S.G. § 2B1.1(b)(1)(K) explain that as a general rule, the loss amount is calculated by the greater of the actual or intended loss. Actual loss is defined as, “the reasonably foreseeable pecuniary harm that resulted from the offense,” with reasonably foreseeable pecuniary harm defined as, “pecuniary harm that the defendant knew or, under the circumstances, reasonably should have known, was a potential result of the offense.” *United States v. Roudabush*, 578 Fed.Appx. 292, 295 (4th Cir. 2014).

Mr. Stein initially believed this enterprise was operating just as his daytime employer operated, in the gray market. Mr. Stein believed that many of the products shipped to customers were, in fact, the very product that these physicians and clinics had intended to purchase. In the instances where products were manufactured in the US but earmarked for sale overseas such that they bore different labeling and packaging, Mr. Stein understood them to be the same products offered for sale within the US, just at a cheaper price when sold overseas. This is a cornerstone of how the gray market operates.

In *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995), the court vacated the defendant’s sentence when the victims of defendant’s fraud on the FDA had suffered no tangible loss. The drugs these consumers received were “exactly what they purported to be: [drugs] approved by the FDA, manufactured in a certain strength and dosage, and producing the specified therapeutic benefits that the FDA requirements were intended to ensure.” *Id.* at 1341. Similarly, in *United States v. Andersen*, 45 F.3d 217, 221-22 (7th Cir. 1995), the court declined to affirm a loss enhancement where there was no evidence of loss to customers. Likewise, in *United States v. Haas*, 171 F.3d 259 (5th Cir. 1999), lacking evidence to the contrary, “there would be no economic harm done to the customers if they consumed the drugs in ignorance of

the lack of FDA approval and those drugs performed just as well as FDA-approved drugs.” *Id.* at 269.

Admittedly, Mr. Stein did not give proper consideration to the regulations relating to the products that he shipped, but he had no reason to believe that the pharmaceuticals he shipped somehow were not safe and effective. He continued to receive instructions to ship products, often repeatedly to the same customers, a testament to their efficacy. No information was ever relayed to him indicating otherwise. Mr. Stein further believed the products to be properly maintained and shipped to the customer, as he strictly followed the company’s protocol in storing and shipping products. While on occasion a customer returned a product or demanded a refund, those instances were rare and not uncommon for any business to confront. Furthermore, in his narrow capacity as a shipper, Mr. Stein was rarely made aware of a customer’s dissatisfaction with a product. Most importantly, he was never informed of any bodily harm caused by these products or as a result of their shipping process. The government’s suggestion that any drug caused bodily harm to anyone is mere conjecture.

Where the actual loss is unquantifiable, the alternative measure of loss is economic gain to the defendant. *See, e.g., Chatterji*, 46 F.3d at 1340, *Haas*, 171 F.3d at 269. This is the correct method to measure the loss for Mr. Stein, as he did not reasonably foresee any pecuniary harm to the customers who received products from him. In his confined position as a shipper, he had no knowledge of the purchase price that customers paid, leaving him completely incapable of ever deducing a monetary loss that a customer could suffer. He similarly had no concept of how much TC Medical Group paid for these pharmaceuticals, the profit received from their sale, or the purchase price of these products from other wholesalers or retailers. Unlike the other

members of this enterprise, he was paid per shipment, unaware of the gains to the company, or even if they were profitable.

The obtuse nature of the sentencing Guidelines makes its application in this case inappropriate because § 2B1.1 applies a loss amount without any consideration of the fact that the customers of TC Medical Group did, in fact, receive effective pharmaceuticals. To Mr. Stein's knowledge, these pharmaceuticals were chemically identical to those sold domestically under FDA regulation, intended for sale overseas, but sold by TC Medical Group to domestic customers at a reduced price. The repeat business of TC Medical Group by clinics and physicians, those familiar with the expected results of these pharmaceuticals, evidences the customers' gain and satisfaction with these pharmaceuticals. If any loss is appropriate at all, it is one based on the loss to the manufacturer that received less because the product purchased was one for sales overseas instead of one for sale within the US. This loss should be calculated by the amount the manufacturer would receive for the sale of the product in the US offset by the amount it received by the purchase of the overseas intended product. As this loss amount, or any possible loss to the customers of Mr. Stein's shipments, is too difficult to quantify, the loss attributable to Mr. Stein should be in the range of \$120,000 to \$200,000, his gain from his involvement with TC Medical Group.

CONCLUSION

Probation is the appropriate sentence for Mr. Stein. The circumstances of his crime, his lack of criminal history, his involvement with his family and steady employment all lead to the conclusion that Mr. Stein's sentencing warrants a downward variance. Also supporting this variance is the fact that he poses no threat to society and similarly situated defendants have been sentenced to probation. Finally, a sentence of incarceration would preclude Mr. Stein's ability to

support his ex-wife and daughter who depend solely upon him for their livelihood. Incarceration removes this financial support not only for the length of incarceration, but also afterward, as Mr. Stein will lose his job and have difficulty obtaining a new one.

For the reasons set forth above, we respectfully ask the court to sentence Mr. Stein to a non-Guidelines sentence of probation.

Respectfully submitted,

HANOCH DAVID STEIN

By: _____/s/_____
Counsel

James W. Hundley (VSB No. 30723)
Erin L. Blanch (VSB No. 75020)
BRIGLIAHUNDLEY, P.C.
1921 Gallows Road, Suite 750
Vienna, Virginia 22182
703-883-0880
703-883-0899 (fax)
jhundley@brigliahundley.com
eblanch@brigliahundley.com

Ari Casper
The Casper Firm, LLD
One South Street, 27th Floor
Baltimore, MD 21202
Vienna, Virginia 22182
410-989-5097
410-630-7776 (fax)
acasper@casperfirm.com

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2015, I electronically filed the foregoing Sentencing Memorandum with the Clerk of the Court using the CM/ECF system, which will send notice of said filing (NEF) to the following:

Alexander T. H. Nguyen
Assistant United States Attorney
Office of the United States Attorney
2100 Jamieson Avenue
Alexandria, VA 22314
703-299-3700
Email: Alexander.nguyen@usdoj.gov

Jay V. Prabhu
Assistant United States Attorney
Office of the United States Attorney
2100 Jamieson Avenue
Alexandria, VA 22314
703-299-3700
Email: jay.prabhu@usdoj.gov

Kellen Dwyer
Assistant United States Attorney
Office of the United States Attorney
2100 Jamieson Avenue
Alexandria, VA 22314
703-299-3700
Email: kellen.dwyer@usdoj.gov

/s/

James W. Hundley (VSB No. 30723)
Erin L. Blanch (VSB No. 75020)
BRIGLIAHUNDLEY, P.C.
1921 Gallows Road, Suite 750
Vienna, Virginia 22182
703-883-0880
703-883-0899 (fax)
jhundley@brigliahundley.com
eblanch@brigliahundley.com